IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
WITCHITA FALLS DIVISION

THE STATE OF FLORIDA, *et al.*, *Plaintiffs*, v. U.S. FOOD AND DRUG ADMINISTRATION, *et al.*, *Defendants.*	No. 7:25-cv-00126-O

REPLY IN SUPPORT OF DEFENDANTS' MOTION TO STAY PROCEEDINGS

Two relevant developments have occurred since Defendants filed their Motion to Stay or, Alternatively, Dismiss. ECF Nos. 20, 20-1. First, Plaintiffs' response clarified that they do not oppose a stay of some duration, which they agree "would promote 'economy of time and effort for [the Court], for counsel, and for litigants.'" ECF No. 56 (Pl. Resp.) at 6.[1] That alone warrants granting a stay.

Second, a motions panel of the Fifth Circuit stayed the 2023 REMS Modification pending appeal in a related case. *Louisiana v. FDA*, No. 26-30203, 2026 WL 1194924 (5th Cir. May 1, 2026). The panel accepted theories of standing similar to those Plaintiffs

[1] Plaintiffs claim that Defendants' motion misrepresented their position. Pl. Resp. 3; *see also id.* 3-5. However, on March 13, 2026, at 11:27 AM ET, one of Plaintiffs' counsel emailed the following: "Please note that Florida and Texas oppose the motion to stay. We intend to file a response in opposition to your stay motion." Defendants accurately reported that position. ECF No. 20, at 2.

assert here. *Id.* at *4-*6. *But see Washington v. FDA,* 108 F.4th 1163 (9th Cir. 2024). Intervenor-Defendants, who market mifepristone products, sought emergency relief from the Fifth Circuit's ruling in the Supreme Court. That request remains pending, and the Fifth Circuit merits panel has not yet decided the appeal.

Together, these developments warrant staying this case until the later of (1) completion of FDA's review of the mifepristone REMS or (2) resolution of the appellate proceedings in *Louisiana*, including disposition of any petition for a writ of certiorari. Although FDA does not agree with Plaintiffs' characterization that FDA is "substantively reconsidering" prior agency actions,[2] the agency's new review includes consideration of a variety of actions (including withdrawal of approval or restoring previous REMS requirements) raised in citizen petitions submitted to the agency that could moot some or all of Plaintiffs' claims. ECF No. 56-1, ¶ 5. As FDA explained, its review "will necessarily result in a *new* agency decision," and Plaintiffs "may seek judicial review at that time" if they believe the new decision adversely affects them. ECF No. 20-1, at 4 (emphasis added). By also deferring any review until after appellate proceedings in *Louisiana* are resolved, both the parties and this Court will receive the

[2] As Plaintiffs' counsel's declaration makes clear, this is purely Plaintiffs' characterization, not FDA's. ECF No. 56-1, ¶¶ 3, 5, 7, 8. FDA's review of the mifepristone REMS entails consideration of all arguments and information currently before the agency. FDA is not "reconsidering" prior decisions based on the records before the agency at the time those decisions were made. *Cf.* 21 C.F.R. § 10.33(e) (noting that a petition for reconsideration "may not be based on information and views not contained in the administrative record on which the decision was made"). To be sure, a new action from FDA may well have the practical effect of undoing a prior agency action, but any such action would remain a *new* agency decision, not a reconsideration of an old one.

benefit of any ruling by the Fifth Circuit and Supreme Court regarding very similar theories of standing.

The Court should therefore stay this case and defer consideration of FDA's motion to dismiss until after the agency's review is complete and appellate proceedings in *Louisiana* are resolved. If further review is necessary at that time, the Court should order supplemental briefing on Defendants' motion to dismiss. Alternatively, the Court should stay this case and order FDA to file a report on the status of its review by October 7, 2026, as required by Judge Joseph, *see Louisiana v. FDA*, No. 6:25-cv-01491-DCJ-DJA, 2026 WL 936958 (W.D. La. Apr. 7, 2026). In any event, no party disputes that a stay of some duration is appropriate.[3]

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Respectfully submitted,

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[3] Counsel have reported the following positions on staying the case through the later of the completion of FDA's review or the resolution of appellate proceedings in *Louisiana*: Plaintiffs "oppose staying the case for an indefinite period of time"; GenBioPro supports FDA's request; Danco also consents to FDA's request.

Counsel for Defendants